

Notice of Allowability

Application No.

10/088,113

Examiner

Jennifer Kim

Applicant(s)

LAREIDA, JUERG

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to May 29, 2007.
2. ☒ The allowed claim(s) is/are 2,3, 5, 7, 8, 15 and 16 (renumbered as 2,3,1,4,5,6 and 7 respectively).
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Jennifer Kim
Primary Examiner
Art Unit 1617

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. James J. Napoli on September 27, 2007.

The application has been amended as follows:

In the Claims:

In claim 5, line 2, the phrase "by application to a patient in need there of" has been **replaced with** - - - - -by administration to a patient suffering from neuropathy, - - - -.

In claim 5, line 25, the phrase "a degenerative neuropathy," has been **deleted**.

In claim 7, line 2, the phrase "a patient" has been **replaced with** - - -the patient-
- -.

In claim 8, line 2, the phrase "a patient" has been **replaced with** - - -the patient-
- -.

In claim 15, line 2, the phrase "a degenerative neuropathy," has been **deleted**.

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In claim 16, line 2, the phrase "application to a patient in need thereof" has been replaced with - - - - - administration to a patient suffering from the polyneuropathy, - -

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious the claimed method for a chemotherapeutic treatment of a neuropathy characterized by application to a patient suffering from the neuropathy, from 1-100mg/day of a pharmaceutical agent comprising a compound of formula (I) set forth in claims 2, 3, 5 and 16.

The cited prior art of record, Brewer et al. teach that sildenafil citrate therapy in med with Parkinson's disease is effective with minimal side effects. However, Brewer et al. do not teach the treatment of specific neuropathies such as a peripheral diabetic polyneuropathy, gastroparesis, a toxic neuropathy and a metabolic neuropathy. There is no motivation of treating such specific neuropathies without specific teaching or

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suggestions from the prior art. Therefore, there is no reasonable expectation of successfully treating the neuropathies without the teachings from the prior art.

The cited prior art of record, Doherty, Jr. et al. (U.S. Patent No. 6,037,346) teaches a method for treating erectile dysfunctions in a mammalian male individual comprising administering a phosphodiesterase inhibitor including sildenafil citrate. The cited prior art, de Tejada (U.S. Patent No. 6,277,884 B1) teaches that sexual dysfunctions are attributable to neuropathy. However, the claims are now amended to separate the patient population of those actually suffering from the specific neuropathy rather than a patient population who are in "need" of treating the specific neuropathies. Further, the patient having erectile dysfunction do not always attribute to neuropathy. Therefore, there is no reasonable expectation of successfully treating those specific neuropathy in light of Doherty et al. in view of de Tejada without specific teaching or suggestions from the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
September 27, 2007